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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/817,102

Applicant(s)

CAUFIELD ET AL.

Examiner

SARAE BAUSCH

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11-15,20,22-24,26-29 and 32-46 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5-9,11-15,22-24,26,27,29 and 32-44 is/are rejected.
- 7) ☒ Claim(s) 4,20 and 44-46 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(c), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(c) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/2007 has been entered.
2. Currently, claims 1, 3-9, 11-15, 20, 22-24, 26-29, and 32-46 are pending in the instant application. Claims 2, 10, 16-19, 21, 25, and 30-31 have been canceled, claims 37-46 have been added and claim 28 is withdrawn. This action is written in response to applicant's correspondence submitted 12/27/2007. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. Any rejections not reiterated in this action have been withdrawn as necessitated by applicant's amendments to the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. **This action is Non-Final.**

Election/Restrictions

3. Newly submitted claims 37-46 is directed to an invention that contains species that are independent or distinct from the invention originally claimed for the following reasons: claims 37-46 are directed to patentably distinct species: biological, chemical and radiological agents. The species are independent and distinct because the agents are structurally and functionally

distinct. For example a biological agent comprises living organisms that replicates in a host organism while a chemical agent comprises an organic compound that attacks a biological pathway, and a radiological agent comprises exposing a host to radiation which causes mutagenic mechanisms in the host.

Since applicant has received an action on the merits for the originally presented invention with regard to the election of species biological agents, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the election of the species, biological agents, for claims 36-46 is under examination.

Withdrawn Objections/Rejections

4. The rejection of claims 1, 3, 11-16, and 22-27 under 35 USC 102(e), made in section 11, of the previous office action mailed 07/27/2007 is withdrawn in view of the amendment to the claims.
5. The objection of claims 29, 32-36 made in section 15 of the previous office action mailed 07/27/2007 is withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1, 3, 5-9, 11-15, 22-24, 26-27, 37-43 are rejected under 35 U.S.C. 102(a) as being anticipated by Hoffmaster et al. (Emerging Inf. Diseases, 2002, Vol 8, No. 10, supplement, p. 1-12).

With regard to claim 1, 3, 6-9, 11, and 22-24,37-38, Hoffmaster et al. teach evaluation and validation of RT-PCR for identification of *Bacillus anthracis* in environmental samples (See page 1, 2nd paragraph). Hoffmaster et al. teach elution of swab specimens and environmental samples in a aqueous solution (collection integrity is preserved, claim 22) (see page 2, last paragraph cont'd to page 3). Hoffmaster et al. teach a wide variety of samples were tested including dust and vacuum cleaner debris (samples derived from street debris material, sample derived from a street sweeper machine, sample collected in predetermined traceable route claim 3, 6-9, 11) (sample from within a collection bin, claim 23-24) (see Real-time PCR in environmental samples, page 5).

With regard to claim 5 and 41, Hoffmaster et al. teach real-time PCR to detect *B. anthracis* (see page 1, 2nd full paragraph).

With regard to claim 12-15, 37-40 and 42, Hoffmaster et al. teach testing the environmental sample by PCR and culture to determine the presence of *B. anthracis*. Hoffmaster teaches that 35 samples were positive by both methods and only 7 were positive by culture only, 4 positive by PCR only (see Real-time PCR in environmental samples, page 5 and page 7, last two paragraphs). Therefore, Hoffmaster, teaches assaying for the presence of a biological agent by comparing the level to a normal level in one or more routes (claim 12-14) (positive result in either PCR or culture). Hoffmaster teaches assaying for an increase or decrease relative to an earlier assay (claim 15-16) (PCR versus culture assay).

With regard to claim 25-27, Hoffmaster et al. each testing environmental samples by PCR by elution of swab specimens and environmental samples in an aqueous solution (see page 2, last paragraph con't to page 3). Hoffmaster et al. teach testing the environmental specimens by real time PCR for the detection of B. anthracis (biological agent) (see real time PCR of environmental specimens, page 5). Hoffmaster et al. teach reporting the results of the PCR analysis of the samples (see page 5 and page 7).

Response to Arguments

8. The response traverses the rejection on page 12 of the response mailed 12/27/2007. The response asserts that Hoffmaster does not expressly disclose samples derived from street debris collected continuously along a route undertaken by a street sweeper machine. The response asserts that although Hoffmaster discloses vacuum debris, street debris samples derived from a route undertaken by a street sweeper machine is not necessarily be present in the subject matter disclosed by Hoffmaster. This response has been thoroughly reviewed but not found persuasive. Hoffmaster et al. discloses vacuum cleaner debris. The specification defines a street sweeper machine on page 7 lines 5-10 that a street sweeper machine is a machine that cleans and or collects trash from floors or other places where people gather. The specification further teaches that a street sweeper machine embodies a street sweeper and analogous apparatuses such as floor buffers, including smaller or modified versions used within buildings. Based on the definition and examples provided for in the specification a vacuum cleaner and also vacuum cleaner debris (debris from a vacuum cleaner) is encompassed by the term street sweeper machine. A vacuum cleaner cleans floors and is a modified smaller version of a street sweeper that is used within buildings. Therefore, the teachings of Hoffmaster to include vacuum cleaner debris does

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disclose samples derived from street debris collected continuously along a route undertaken by a street sweeper machine, as defined in the specification. Therefore, Hoffmaster et al. anticipates the claimed invention.

For these reasons, and the reasons made of record in the previous office actions, the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schlimme et al. (App. Environ. Micro. June 1999, pp. 2754-2757).

Schlimme teach a rapid bioassay that uses tetrahymena pyriformis to assess overall bacterial toxicity (see pg. 2754, 1st column, 3rd para.). Schlimme et al. teach this test can be used

for the detection of bacterial toxicants and for the risk assessment of bacterial strains. Schlimme et al. teach determining the presence of multiple different bacterial strains, including two bacillus strains by adding bacteria to *T. pyriformis* (see pg. 2754, 2nd column). Schlimme et al. teach analysis of *B. cereus*, two different strains and *B. thuringiensis* as well as *E. Coli*. Schlimme et al. teach that *E. coli* strain was concentrated 10 to 100 fold within *T. pyriformis* (see table 2) and teach that *B. cereus* and *B. thuringiensis* were not toxic to *T. pyriformis* (see table 3). Schlimme et al. does not teach the analysis of *B. anthracis*.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the method of assessing overall bacterial toxicity of *Bacillus cereus* and *Bacillus thuringius* as taught by Schlimme to include *Bacillus anthracis*, to improve the method by Schlimme et al.. The ordinary artisan would have been motivated to improve the method of analyzing the toxicity of bacterial to include *Bacillus anthracis* because Schlimme et al. teaches the use of *T. pyriformis* with multiple different bacterial species of *Bacillus*, including *B. cereus* and *B. thuringius* and the skilled artisan would have been motivated to include multiple other bacterial species and strains, including *B. anthracis*. The ordinary artisan would have had a reasonable expectation of success that the use of *B. anthracis* could be used in the method of Schlimme et al. because Schlimme et al. teach that the use of two different bacillus species, *B. cereus* and *B. thuringiensis* function in the same manner in the presence of *T. pyriformis* (see table 3). It would have been obvious to one skilled in the art to substitute one *Bacillus* species for another species in order to achieve the predictable result of detecting *Bacillus* species by *T. pyriformis*, as taught by Schlimme et al.

12. Claim 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schimme as applied to claim 29 and further in view of Weinbauer (App. Environ. Micro. Oct 1998, pp. 3776-3783) and Agrawal et al. (Current Science 2002, vol. 83, pp. 697-699)

The method of Schimme is set forth in section 11 above. Schimme does not teach the use of a membrane or temperature effective to kill vegetative bacteria.

Weinbauer et al. filtration of bacterial communities by filtering through a 10 μm pore size Nitex screening filter followed by a 3 μm pore size filter and then a .2 μm pore size filter to obtain the bacteria (See pg. 3777, dilution cultures).

Agrawal et al. teach culturing *B. anthracis* followed by heating at 60°C (about 70°C) to inactive any vegetative cells (see pg. 697, 2nd column, 1st paragraph).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the method of Schlimme to include a filtration step to obtain bacteria as taught by Weinbauer and to include a heat step of 60°C to inactive any vegetative cells prior to filtration as taught by Agrawal. The ordinary artisan would have been motivated to improve the method of Schlimme to include a heat step to inactive vegetative cells prior to filtration as taught by Agrawal and include a bacterial filtration step as taught by Weinbauer because Schlimme et al. teaches the use of bacterial and protozoa communities and the skilled artisan would have been motivated to include filtration step to obtain a concentrated and pure sample as taught by Weinbauer and heat inactivation of vegetative cells as taught by Agrawal. The ordinary artisan would have had a reasonable expectation of success that the use of heating *B. anthracis* prior to identification and isolation could be used in the method of Schlimme et al. because each method analyzing the bacterial content in a sample. Furthermore,

the ordinary artisan would have had a reasonable expectation of success that the use of filtration of bacterial communities could be used in the method of Schlimme et al. because Schlimme et al. teach that the use of analyzing bacterial content. It would have been obvious to one skilled in the art to include a predictable results of bacterial filtration and heat inactivation prior to filtration to obtain the predictable result of a concentrated sample as taught by Weinbauer, Agrawal, and Schlimme.

13. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schimme as applied to claim 29 above, and further in view of Weinbauer (App. Environ. Micro. Oct 1998, pp. 3776-3783).

The method of Schimme is set forth in section 11 above. Schimme does not teach the use of a first membrane having a pore size larger than *B. anthracis* and a second membrane having a pore size smaller than *B. anthracis*.

Weinbauer et al. filtration of bacterial communities by filtering through a 10 μm pore size Nitex screening filter followed by a 3 μm pore size filter and then a .2 μm pore size filter to obtain the bacteria (See pg. 3777, dilution cultures).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the method of assessing overall bacterial toxicity as taught by Schlimme to include a filtration step to obtain bacteria, to improve the method by Schlimme et al.. The ordinary artisan would have been motivated to improve the method of analyzing the toxicity of bacterial to include a bacteria filtration step as taught by Weinbauer because Schlimme et al. teaches the use of bacterial and protozoa communities and the skilled artisan would have been motivated to include filtration step to obtain a concentrated and pure

sample as taught by Weinbauer. The ordinary artisan would have had a reasonable expectation of success that the use of filtration of bacterial communities could be used in the method of Schlimme et al. because Schlimme et al. teach that the use of analyzing bacterial content. It would have been obvious to one skilled in the art to include a predictably results of bacterial filtration to include a multiple step filtration system to obtain the predictable result of a concentrated sample as taught by Weinbauer.

14. Claim 35-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schimme as and further in view of Weinbauer applied to claim 34 above, and further in view of Agrawal et al. (Current Science 2002, vol. 83, pp. 697-699)

The method of Schimme and further in view of Weinbauer is set forth in section 12 above. Schimme and further in view of Weinbauer does not teach the use of a first membrane and/or second membrane at a temperature effective to kill vegetative bacteria.

Agrawal et al. teach culturing B. anthracis followed by heating at 60°C (about 70°C) to inactive any vegetative cells (see pg. 697, 2nd column, 1st paragraph).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to improve the method of Schlimme and further in view of Weinbauer, to include a heat step of 60°C to inactive any vegetative cells prior to filtration. The ordinary artisan would have been motivated to improve the method of Schlimme in view of Weinbauer to include a heat step to inactive vegetative cells prior to filtration. The ordinary artisan would have had a reasonable expectation of success that the use of heating B. anthracis prior to identification and isolation could be used in the method of Schlimme et al. and further in view Weinbauer because each method analyzing the bacterial content in a sample. It would have

been obvious to one skilled in the art to include a predictable results of heat inactivation of vegetative cells prior to obtain the predictable result of a concentrated sample.

Conclusion

15. Claims 4, 20, 44-46 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
16. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SARAE BAUSCH whose telephone number is (571)272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application

or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Sarae Bausch/
Primary Examiner, Art Unit 1634